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105TH CONGRESS
1ST SESSION

H. R. 1527

To amend the Federal Food, Drug, and Cosmetic Act with respect to the classification of and performance standards for devices.

IN THE HOUSE OF REPRESENTATIVES

MAY 1, 1997

Mr. UPTON (for himself, Ms. ESHOO, Mr. GREENWOOD, Mr. TOWNS, and Mr. HALL of Texas) introduced the following bill; which was referred to the Committee on Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to the classification of and performance standards for devices.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; REFERENCES TO FEDERAL FOOD, DRUG, AND COSMETIC ACT.

(a) SHORT TITLE.—This Act may be cited as the ''Medical Device Regulatory Flexibility Act''.

(b) REFERENCES TO FEDERAL FOOD, DRUG, AND COSMETIC ACT.—Except as otherwise expressly provided, whenever in this Act an amendment or repeal is expressed

in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act.

SEC. 2. INITIAL CLASSIFICATION.

Section 513(f) (21 U.S.C. 360c(f)) is amended—

(1) in paragraph (1) in the last sentence, by striking ''paragraph (2)'' and inserting ''paragraph (2) or (3)'';

(2) by redesignating paragraphs (2) and (3) as paragraphs (3) and (4), respectively; and

(3) by inserting after paragraph (1) the following new paragraph:

''(2)(A) Any person who submits a report under section 510(k) for a type of device that has not been previously classified and which is classified into class III under paragraph (1), may request that the Secretary classify the device in class I or II, under criteria set forth in subparagraphs (A) through (B) of subsection (a)(1), within 30 days of receiving written notice of the classification. Such request shall describe the device and provide the reasons supporting such person's recommended classification for the device based on specified classification criteria.

''(B) Not later than 60 days after the date of the request for classification under criteria set forth in subparagraphs (A) through (B) of subsection (a)(1), the Secretary shall by order classify the device and notify in writing the person who submitted such request of the classification. Such classification shall be the initial classification of the device for purposes of paragraph (1). Any device which is classified into class III under this subparagraph shall be deemed adulterated within the meaning of section 501(f)(1)(B) until approved under section 515 or exempted from such approval under section 520(g).''.

SEC. 3. DEVICE STANDARDS.

(a) ALTERNATIVE PROCEDURE.—Section 514 (21 U.S.C. 360d) is amended by adding at the end thereof the following:

''Listing of Recognized Standards

''(c)(1) The Secretary may, through publication in the Federal Register, issue notices to identify and list nationally and internationally recognized standards which—

''(A) shall be the special controls to which persons my certify compliance for purposes of the special controls required by section 513(a)(1)(B);

''(B) the Secretary may for purposes of device classification use in establishing the equivalence of one device to another; and

''(C) may be used by the Secretary in considering an application for premarket approval of a class III device.

''(2) The Secretary may remove from the list of standards established under paragraph (1) a standard which the Secretary determines is not reliable for the purpose set out in paragraph (1).

''(3) The Secretary shall accept a certification that a device conforms to a standard listed under paragraph (1), except that the Secretary may, at any time, request the person who submitted the certification to submit the data and information which such person relied upon in making such certification. A person who submitted such a certification shall maintain such data and information for a period of 2 years after the submission of such certification.''.

(b) CONFORMING AMENDMENTS.—

(1) SECTION 514(a).—Section 514(a) (21 U.S.C. 360d(a)) is amended by striking ''established under this section'' each place it occurs and inserting ''established under subsection (b) or listed under subsection (c)''

(2) ADULTERATED DEVICE.—Section 501(e) (21 U.S.C. 351(e)) is amended by striking ''established'' and inserting ''established or listed''.

(3) PROHIBITED ACTS.—Section 301 (21 U.S.C. 331) is amended by adding at the end the following:

''(u) The falsification of a certification under section 514(c)(3) or the failure or refusal to provide data or information requested by the Secretary under such section.''.

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